Complete Summary

GUIDELINE TITLE

Management of stable angina. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Management of stable angina. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2001. 26 p. (SIGN publication; no. 51). [172 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Stable angina

GUIDELINE CATEGORY

Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To present evidence-based recommendations for the management of stable angina pectoris in primary care.

TARGET POPULATION

Adult patients with stable angina

INTERVENTIONS AND PRACTICES CONSIDERED

Investigation and referral

1. Initial assessment, including patient history and clinical examination
2. Laboratory tests, including haemoglobin, fasting blood glucose, and full lipid profile
3. Resting 12-lead electrocardiogram (ECG)
4. Exercise tolerance test
5. Referral to a cardiologist

Management of risk factors

1. Advice to stop smoking and use of tailored self-help materials, individual/group counseling, antidepressants, and nicotine replacement therapy

Assessment and management of hypertension

1. Diet modification
2. Weight loss, as required
3. Measurement of cholesterol levels and use of cholesterol-lowering drugs, as required
4. Aerobic exercise
5. Limiting alcohol consumption
6. Optimization of glycaemic control in diabetic patients

Drug treatment

Secondary prophylactic treatment

1. Aspirin therapy
2. Clopidogrel
3. Statins
4. Angiotensin converting enzyme inhibitors

Short term control of angina symptoms

1. Sublingual glyceryl trinitrate (GTN)

Long term prevention of angina symptoms

1. Beta-blockers (monotherapy or combination therapy)
2. Monotherapy with rate-limiting calcium channel blockers (e.g., diltiazem or verapamil), long-acting dihydropyridines, or potassium channel opening agents in patients intolerant to beta-blockers
3. Monotherapy with oral nitrates, such as isosorbide dinitrate or mononitrate (Note: high-dose nitrate patches are considered but not recommended)
4. Combination therapy of beta-blockers with isosorbide mononitrate, a long-acting dihydropyridine, or diltiazem
5. Addition of a third drug

MAJOR OUTCOMES CONSIDERED

- Survival
- Blood pressure
- Morbidity rates
- Coronary heart disease
- Control of symptoms

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Patient Registry Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline development group reviewed the medical literature and existing guidelines published by a wide range of other bodies, including the North of England evidence-based guideline for the Primary Care Management of Stable Angina. The group decided that the quality and depth of the systematic review undertaken for the North of England guideline was such as to make duplication of this work unnecessary. It was decided to base the Scottish Intercollegiate Guideline Network (SIGN) guideline on the North of England guideline, adapting it to produce a guideline suitable for use within Scotland. The Scottish Intercollegiate Guideline Network acknowledges the debt to the North of England project group and extensive reference is made throughout the guideline to their original document. The Scottish Intercollegiate Guideline Network guideline quotes additional references reviewed by the SIGN guideline group.

Searches for other guidelines or systematic reviews were carried out covering key Internet sites, Embase, Healthstar, Medline, and Pascal. An additional search, covering the same databases, was carried out looking specifically at the management of stable angina and secondary prevention of coronary heart disease in primary care. The main searches were supplemented by material identified by individual members of the development group. All selected papers were evaluated

using standard methodological checklists before conclusions were considered as evidence.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Statements of Evidence:

Ia: Evidence obtained from meta-analysis of randomized controlled trials.

Ib: Evidence obtained from at least one randomized controlled trial.

IIa: Evidence obtained from at least one well-designed controlled study without randomization.

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the

methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "SIGN 50: A Guideline Developer's Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN website.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the group are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline

development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A: Requires at least one randomized controlled trial (RCT) as part of a body of literature of overall good quality and consistency addressing the specific recommendation (Evidence levels Ia, Ib).

Grade B: Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation (Evidence levels IIa, IIb, III).

Grade C: Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV).

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of Scottish Intercollegiate Guideline Network (SIGN) guideline development, at which the guideline development group present their draft recommendations for the first time. The national open meeting for this guideline was held on 27th September 1999 and was attended by 198 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the Scottish Intercollegiate Guideline Network web site for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was also reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The Scottish Executive Coronary Heart Disease Task Group also provided comments on the guideline.

As a final quality control check, the guideline is reviewed by an Editorial Group comprising the relevant specialty representatives on the Scottish Intercollegiate Guideline Network Council to ensure that the peer reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

Each member of the guideline development group then approved the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-C) and level of evidence (Ia-IV) are defined at the end of the â œMajor Recommendationsâ field.

Investigation and Referral

B: Patients with angina should have a resting 12-lead electrocardiogram.

B: Patients with angina and an abnormal resting 12-lead electrocardiogram should be considered for urgent referral and investigation.

B: Patients with angina should be referred for exercise tolerance testing for risk stratification.

B: Patients having an exercise tolerance test to assess prognosis should have the test while taking their normal medication.

Management of Risk Factors

Smoking

B: All patients with angina who smoke should be advised to stop.

A: Brief advice from a health professional, tailored self-help materials, individual and group counselling and antidepressants (with behavioural support) can increase rates of smoking cessation.

B: Nicotine replacement therapy is recommended as part of a smoking cessation program in patients with angina.

Hypertension

B: All those with angina should have blood pressure assessed and managed.

Dietary Factors

B: Patients with angina should modify their diet in line with healthy eating advice:

- increase fruit and vegetable consumption to five portions per day
- increase consumption of oil-rich fish to three portions per week
- decrease total fat consumption, increasing the proportion of monounsaturated fat
- increase starchy food intake and reduce sugary food intake

Obesity and Overweight

C: All patients with coronary heart disease should be actively encouraged to lose weight towards body mass index <25.

Cholesterol

C: All patients with angina should have their cholesterol level measured. If total cholesterol (TC) is $\geq$5.0 mmol/L:

- C: appropriate dietary measures should be recommended and a random non-fasting cholesterol measurement repeated after 6 to 12 weeks.
- A: If required, drug therapy should then be initiated to reduce total cholesterol to <5.0 mmol/L.

Physical Activity

B: All those with coronary heart disease should be encouraged to increase their aerobic exercise levels within the limits set by their disease state.

B: Patients should be involved in decisions about exercise in order to improve perseverance.

Alcohol Consumption

B: Patients with coronary heart disease who consume alcohol should be encouraged to limit their consumption to three units per day for men and two units per day for women.

Diabetes

C: Diabetic patients with angina should make efforts to optimise glycaemic control.

Drug Treatment

A: Patients with stable angina should be treated with aspirin 75 mg daily.

A: In the event of true aspirin intolerance or allergy, clopidogrel 75 mg daily should be considered.

B: Patients who require regular symptomatic treatment should be treated initially with a beta-blocker (unless specifically contraindicated).

B: Patients should be warned not to stop beta-blockers suddenly or allow them to run out.

C: Patients intolerant of beta-blockers and who show no left ventricular systolic dysfunction should be treated with a rate-limiting calcium channel blocker, a long-acting dihydropyridine, a nitrate or a potassium channel opening agent.

A: Oral nitrates can be used as a satisfactory monotherapy, provided they are used in a way which avoids nitrate tolerance (e.g. in an eccentric dosage).

A: In patients taking beta-blockers, add isosorbide mononitrate, a long-acting dihydropyridine or diltiazem.

Definitions:

Grades of Recommendations:

A. Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B. Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation. (Evidence levels IIa, IIb, III)
C. Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Statements of Evidence:

Ia: Evidence obtained from meta-analysis of randomized controlled trials.

Ib: Evidence obtained from at least one randomized controlled trial.

IIa: Evidence obtained from at least one well-designed controlled study without randomization.

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study.

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.

IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The specific type of supporting evidence is explicitly identified in each section of the guideline.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of stable angina might:

- Decrease cardiovascular events
- Increase survival
- Decrease blood pressure
- Decrease morbidity rates
- Decrease coronary heart disease risk
- Prevent long-term symptoms
- Increase symptom control

POTENTIAL HARMS

Exercise tolerance test

- An exercise tolerance test is a low risk investigation even in patients with known ischaemic heart disease, but serious complications occur in 2 to 4 per 1,000 tests. Death may occur at a rate of 1-5 per 10,000 tests.

Nicotine replacement therapy

- Many manufacturers of nicotine replacement therapy caution in the prescription of these products to patients with known cardiovascular disease. Nicotine may contribute to cardiovascular disease, presumably by hemodynamic consequences of sympathetic neural stimulation and systemic catecholamine release. However, analyses have now documented the lack of association between nicotine replacement therapy and acute cardiovascular events and the risks of nicotine replacement therapy for smokers, even for those with underlying cardiovascular disease, are small and are substantially outweighed by the potential benefits of smoking cessation.

Aspirin

- The most common side effect related to aspirin is dyspepsia. Non-statistically significant increases in the incidence of gastro-intestinal bleeding have been reported with increasing doses of aspirin in some studies.
- True aspirin allergy manifests itself as angio-oedema or bronchospasm, but is rare.

Beta-blockers and calcium channel blockers

- One meta-analysis reported that calcium channel blockers were associated with a greater number of adverse events compared with beta-blockers in trials of patients with stable angina. Other papers have indicated frequent adverse effects with beta-blockers and attributed lower adverse-effect profiles to calcium channel blockers.
- Acute withdrawal of beta-blockers has been associated with an increase in coronary events in the months after stopping treatment in hypertensive patients.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline addresses the management of stable angina pectoris. The information and advice given does not apply to the patient with unstable angina describing prolonged episodes of severe angina, increasingly frequent angina, or angina at rest. Also, angina recurring early following initially successful coronary artery bypass grafting (CABG), or percutaneous transluminal coronary angioplasty (PTCA), falls out with the context of stable angina, and should prompt early specialist referral.

The guideline development group assumes that health care professionals will use general medical knowledge and clinical judgement in applying the principles and specific recommendations of this document to the management of individual patients. Recommendations may not be appropriate for use in all circumstances;

all patients should continue to be considered as individuals and many may fall outside the scope of this guideline. This may be particularly true in those of advanced age or with multiple medical problems. Decisions to adopt any particular recommendation from the national guideline locally can only be made in the light of available resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health System Trust and is an essential part of clinical governance. It is acknowledged that every Trust cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Given the substantial body of evidence on how patients with angina should be treated, attention needs to be focused on implementing this evidence. The size of this task is considerable. The Scottish Health Survey found the overall prevalence of ischemic heart disease in Scotland among male and female patients aged from 16 to 74 years to be 6.4% and 4.6% respectively.

Systems to Improve Care for Patients with Angina

Given its prevalence, most patients with stable angina are cared for most of the time in general practice. Several systems of care have been suggested as means to improve on routine care. These include nurse-run clinics, cardiac liaison nurses, postal prompts to general practitioners and patients, audits and other data collection exercises, computer prompts for use during consultations, expanded roles for community pharmacists and multidisciplinary approaches with input from dietitians and physiotherapists. To date, only some of these approaches have been subject to robust evaluations. There have been five randomized trials either wholly in primary care or at the primary/secondary care interface.

See section 5 of the original guideline document for a discussion and recommendations related to structured care and follow-up with nurse-led clinics, audit and feedback, improving communication at the primary/secondary care interface, and other approaches.

Outcome Indicators

- Symptom control assessed by patients
- Emergency admission for coronary heart disease
- Rates of sudden death, myocardial infarction, angioplasty, coronary arterial bypass graft

- Rates of smoking cessation
- Achievement of blood pressure control, total cholesterol, weight and physical activity targets

Key points for audit are identified in the original guideline document.

The guideline developer refers users to the section of the original guideline document titled "Implementation and Audit" for additional information.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Management of stable angina. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2001. 26 p. (SIGN publication; no. 51). [172 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Apr

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Charles Swainson (Chairman); Dr Neil Campbell (Methodologist); Dr Neil Dewhurst; Dr Robert Finnie; Sister Janice Fraser; Mr Robin Harbour; Professor Lee Kennedy; Mr Stephen McGlynn; Dr Donald McLeod; Dr Caroline Morrison; Dr Ashley Mowat; Dr Moray Nairn; Dr Sue Vincent; Dr Steven Walton.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned, e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry; a non-personal interest involves payment which benefits any group, unit or department for which the individual is responsible, e.g., endowed fellowships or other pharmaceutical industry support. SIGN guideline group members should be able to act as independently of external commercial influences as possible, therefore, individuals who declare considerable personal interests may be asked to withdraw from the group. Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline was issued in 2001 and will be reviewed in 2003 or sooner if new evidence becomes available.

Any amendments to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Management of stable angina. Scottish Intercollegiate Guidelines Network, 2001 Apr. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research and Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- A background paper on the legal implications of guidelines. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network.

PATIENT RESOURCES

The following, published as an annex to the original guideline, is available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

- Annex 6. Example patient information leaflet. In: Management of stable angina. Edinburgh (UK): Scottish Intercollegiate Guidelines Network, 2001. pp. 18-9. (SIGN publication; no. 51).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on October 17, 2001. The information was verified by the guideline developer as of December 17, 2001.

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